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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,162	11/10/2000	Guillermo J. Tearney	187718/US - 475387-00245	3219

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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/709,162	TEARNEY ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-160* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 7, 2009 have been fully considered but they are not persuasive.

At the bottom of page 28, the Applicant argues an interpretation posed by the Examiner in which "the structure" is the image pick-up device. This interpretation is no longer applicable to the claims and, therefore, will not be addressed. The interpretation discussed at the top of page 29 is relevant, in which a prism is the dispersive element. Lenses **40** and **41** are lenses that direct illumination light into the optical fiber. This optical fiber then directs the light to the prism and then through the transparent window, which ultimately illuminates the tissue. Therefore, there is a lens arrangement being used with a dispersive element to illuminate the structure, wherein the structure is the tissue. Furthermore, "the optical shield **12** is a transparent enclosure made of fused silica, glass, or sapphire or other optically transparent material (column 7, 57-63)." Therefore, the optical shield is, in its own right, a lens.

On page 31, the Applicant argues that Olinger in combination fails to teach a fluid displacement arrangement acting on the dispersive arrangement. Olinger teaches the use of a saline solution being used to clear the area for examination to allow for better viewing. Furthermore, Olinger teaches methods in which to keep the optical elements from fogging. It would have been obvious to one of ordinary skill in the art to use the teachings of Olinger, such teachings being to use a fluid displacement structure and method, to allow better visualization of the area being examined. This would include

clearing the area as well as keeping the optical elements (which would include the dispersive arrangement) clear and, therefore, able to obtain crisp, clear images of the area being examined.

On page 32, the Applicant argues that Kittrell, as well as the other references, fails to teach or suggest the capability of providing “at least 100 spectrally-resolvable points on the sample, at least because no lens is disclosed to be in combination with the dispersive arrangement." The Examiner respectfully disagrees that Kittrell fails to teach a lens arrangement in combination with the prism. Therefore, the Examiner maintains that Kittrell is capable of providing at least 100 spectrally-resolvable points on the sample, thereby continuing to read on these claim limitations.

At the bottom of page 32, the Applicant argues that "the optical fiber has an end portion that is provided at or near a position of an image plane of the at least one portion which is established by the lens” is not taught. The Examiner does not disagree that this description is absent from Kittrell. However, it is obvious that the end of the optical fiber, and therefore, the endoscope would at least be *near* an image plane which is established by the lens. In this manner, the lens would be the optical shield **12**. However, even in the interpretation of the lenses **40** and **41**, the term “near” is indefinite.

On page 33, the Applicant argues that Kittrell does not generate any image which is based on a plurality of wavelengths of the electromagnetic radiations. The Examiner respectfully disagrees. This is discussed at column 19, lines 37-57 of Kittrell.

Claim Objections

Claims 101, 103 and 155 are objected to because of the following informalities:

In claim 101, “lest” should be “least.”

In claim 103, the Examiner believes there to be missing language. For example, "to enhance visualization of a tissue associated with the structure [sic] acts on the dispersive arrangement."

Claim 155 is identical to claim 149 and should be cancelled.

Appropriate correction is required.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Claims 149, 150 and 151 appear twice in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68-75, 81-82, 84-87, 89-95, 101-102, 104-107, 109-116, 118-128, 130, 137-140, 142-145 and 147-157 are rejected under 35 U.S.C. 102(b) as being

anticipated by Kittrell et al. (US Patent No. 5,318,024) – herein referred to as Kittrell. Kittrell discloses a laser endoscope for generating a spectrally resolved spatial (therefore, at *least* two-dimensional) image of tissue. Kittrell illustrates at least one lens arrangement in Figures 21 and 22 with numeral **40** and **41**, which guides light into optical fibers. Furthermore, Kittrell teaches that the shield **12** maybe use to control spot size by means of lenses inserted within the shield (column 5, lines 33-34). Also, Figure 23 illustrates a reflective mirror lens grating combination **68** at the return end of the device. In several embodiments of Kittrell, a lens, multiple lenses, holographic elements, gratings, prisms or a mirror can be used to control the location and divergence of laser light and return fluorescence or scattered light (column 13, lines 64-68). These elements (a lens, multiple lenses, holographic elements, gratings, prisms or a mirror) can be controlled by wires. Light from conventional sources may be used broadband, or it may be filtered or dispersed (column 20, lines 59-62). The laser catheter can be used to penetrate most types of tissues (column 6, lines 5-21), thereby modifying a property of the structure. As illustrated in Figure 25, the distal ends of the optical fibers are at different angles and column 8, lines 57-60 states that the distal ends of the optical fibers are optically polished. As seen in Figure 17C, the light emitted from the end of the probe is made to overlap.

Regarding claims 142-145, it is inherent that the dispersive arrangement will provide a particular number of spectrally resolvable points because the image is created by the light that is dispersed by this arrangement. “A particular number” is not descriptive or limiting and could be any number from zero to infinity.

Regarding claim 147, Kittrell teaches "Spot size can also be varied by means of lenses inserted within the shield..." which places a lens proximate the dispersive prism, which is proximate the end of an optical fiber (*see* Figure 13B).

Regarding claim 148 of the current application, claim 1 of Kittrell states, "processing the separated light received by the detector with a computer such that the spectrally resolved light provides a displayable spatial image of the illuminated tissue."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 83, 88, 103, 108, 117, 129, 131-136, 141, 146 and 158-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Olinger et al. (US Patent No. 3,941,121) – herein referred to as Olinger. Kittrell is discussed above in the rejection of claims 68, 89, 113, 125. However, Kittrell fails to provide a fluid displacement arrangement. Olinger teaches a needle endoscope including a hollow needle of about 18-gauge (*see* Abstract). To clear the area for better viewing in certain situations, a syringe can be connected to a luer lock, associated with the coupling, and warm normal saline solution can be injected through the electrode channel (column 10, lines 32-40). It would have been obvious to combine the teachings of Olinger with the device of Kittrell in order to provide operative visual supervision of a treatment procedure performed through an operative channel of the needle and which his small enough to be universally acceptable for introduction into previously inviolate tissue area without resorting to open surgery techniques (column 2, lines 56-62).

Regarding claims 146, it is inherent that the dispersive arrangement will provide a particular number of spectrally resolvable points because the image is created by the light that is dispersed by this arrangement. "A particular number" is not descriptive or limiting and could be any number from zero to infinity.

Claims 76-78 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Webb et al. (WO 99/44089) – herein referred to as Webb. Kittrell is discussed above in the rejection of claims 75 and 95. However, Kittrell fails to teach a specific number of resolvable points that make up the image. Webb

teaches that the number of resolvable points is related to the total bandwidth of the source and the bandwidth of the spectrum. The number of resolvable points may be any number governed by Equation (2) on page 3. An example is provided on page 4. Absent the showing of criticality, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create an image with any number of resolvable points based on the equation of Webb as a matter of design choice.

Claims 79-80 and 99-100 rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Baker et al. (US Patent No. 5,275,594) – herein referred to as Baker. Kittrell discloses a catheter used for diagnosis and removal of arterial or vascular obstructions (column 1, lines 14-16). See the previous description of Kittrell in the rejection of claims 68 and 89. However, Kittrell does not explicitly disclose a diameter for the probe. Baker teaches that the diameter of arteries is on the order of one to a few millimeters (column 1, lines 40-41). Therefore, it would be obvious to one of skill in the art at the time the invention was made to design the probe of Kittrell to have a diameter of less than about one millimeter in order to allow the device to enter any location in the arteries and vasculature of the patient, based on the teaching of Baker.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

JMK